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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,734	10/06/2000	Ib Mendel-Hartvig	10806-129	1611

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/07/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/582,734

Applicant(s)

MENDEL-HARTVIG ET AL.

Examiner

Gary W. Counts

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 February 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.  
2. ☐ The proposed amendment(s) will not be entered because:  
(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ they raise the issue of new matter (see Note below);  
(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.  
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.  
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:


Claim(s) allowed: \_\_\_\_\_

Claim(s) objected to: \_\_\_\_\_

Claim(s) rejected: 1-4 and 6-33

Claim(s) withdrawn from consideration: \_\_\_\_\_

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.  
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.  
10. ☐ Other: \_\_\_\_\_

  
Gary W. Counts  
Examiner  
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## DETAILED ACTION

### Attachment to Advisory Action

Continuation of 5 NOTE: Applicant argues that Dafforn does not teach a method or device wherein flow is initiated by adding liquid to each zone in such a way that liquid<sub>n+1</sub> added to the application zone LZ<sub>n+1</sub> contacts the flow matrix substantially simultaneously and is transported through the matrix immediately after liquid<sub>n</sub>, added to the nearest downstream application zone LZ<sub>n</sub>. This is not found persuasive because of reasons stated in the previous office action.

Applicant argues that Dafforn does not teach liquid reagent added simultaneously with a sample is transported through a matrix immediately after the sample, instead, applicant asserts that Dafforn teaches that sample and developer solution containing enzyme substrate, added simultaneously to the matrix result in a complex which is carried to the detection zone. This is not found persuasive because it appears that Applicant is trying to assert that two separate liquid fronts are moving toward the detection zone, one containing analyte (i.e. sample), and the other containing the labeled reagent. And that a complex between the analyte and the labeled reagent is not formed prior to both liquid-fronts reaching the detection zone. If this is a correct interpretation of the argument, it is not found persuasive because it is not on point. The claims are not limited to a method where the labeled reagent is moving in a separate front, i.e. behind a sample liquid. Instead, the claims recite an embodiment where the labeled reactant is located in the same zone where sample is added, (i.e. LZ<sub>n</sub>-R\* and LZ<sub>n</sub> with n'  $\geq$  n), since n is recited as the position of the application zone (LZ<sub>n</sub>), the

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indication that  $n''$  is  $\geq n'$  is interpreted as an embodiment where the sample application zone and the zone for the labeled reactant is the same; i.e. Dafforn, column 24, lines 23-46. In this case, a complex between the analyte and the labeled reactant is formed when sample is added to  $LZ_{n'}$ , and this complex is moving in front of any liquid that is added to the other liquid addition zones. Because the claims do not make clear what "liquid" may be added to the various zones, this "liquid" could be buffer or substrate solution, in which case, after the complex of Dafforn reaches the detection zone, the bound complex acts on any substrate solution that subsequently enters the detection zone, resulting in a color change. These teachings are seen to be the same as those of the instant claims.

Applicant argues that the complex is carried by the moving developer solution to the detection zone where it binds. This is not found persuasive because regardless if the developer is added or not the complex will flow toward the detection zone. The addition of developer after the complex would flow behind the complex. If the complex and developer are carried together the reaction would occur before the detection zone. Dafforn clearly states (col 24, lines 35-37) that the reaction occurs at the detection zone. Therefore, the complex binds to the immobilized antibody and then the developer reacts to produce a color change. Thus, Dafforn reads on the instantly recited claims.

Applicant argues that Robinson does not resolve the deficiencies of Dafforn. Specifically, Applicant argues that Robinson does not teach or suggest a method or device as recited in claims 1 and 18 employing at least one analytically detectable biospecific affinity reactant and at least one firmly anchored biospecific reactant in a

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detection zone, with the arrangement of liquid application zones and liquid flows as recited in claims 1 and 18. This is not found persuasive because Examiner has not relied upon Robinson for these limitations, as stated above Dafforn teaches these limitation. Examiner has relied upon the Robinson reference for teaching the advantages of using calibration zone in a flow matrix.

Applicant argues that the deficiencies of Dafforn are not resolved by Self. Specifically, Applicant argues that Self does not teach a method or device for determination of an analyte in a sample and a flow matrix employing a combination of biospecific affinity reactants and liquid application zones and flow as defined in claims 1 and 18. This is not found persuasive because Examiner has not relied upon Self for these limitations. Once again as stated above Dafforn teaches these limitations. Further, Dafforn et al specifically teach that the device may be utilized in any number of assay wherein absorbent material is utilized to assist the flow of liquid away from a contact portion where the absorbent material is contacted with a medium containing the analyte to be determined or reagents for analyzing for the analyte (col 4, lines 11-16). Further, Dafforn et al disclose that the device can be used to detect autoimmune antibodies and antibodies to allergens (col 5, lines 1-6). Since, Self et al disclose that immunoassays are used for the detection and/or determination of autoimmune disease. It would have been obvious to one of ordinary skill in the art to combine the teachings of Dafforn et al and Self et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary Counts  
Examiner  
Art Unit 1641  
March 12, 2003



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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03/29/03